IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

LUZ LECHUGA, Plaintiff, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG; BOEHRINGER INGELHEIM INTERNATIONAL GMBH; and ELI LILLY & COMPANY, Defendants.	)	Case No. 5:17-cv-00728-DAE JURY TRIAL DEMANDED

DEFENDANTS BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. AND ELI LILLY AND COMPANY'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT AND MEMORANDUM IN SUPPORT

Pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6), Defendants Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") and Eli Lilly and Company ("Lilly") (together, "Defendants")[1] submit this Motion to Dismiss Plaintiff's Complaint [D.E. 1] for failure to state a claim upon which relief can be granted.

INTRODUCTION

This case arises out of Plaintiff Luz Lechuga's alleged development of diabetic ketoacidosis ("DKA") that she attributes to her use of Jardiance. Jardiance is a prescription drug approved by the United States Food and Drug Administration ("FDA") as safe and effective for the treatment of Type 2 diabetes. BIPI holds the New Drug Application ("NDA") for Jardiance, and BIPI and Lilly co-market the product.

Plaintiff's Complaint fails to state a claim upon which relief can be granted for four reasons. *First*, all of Plaintiff's claims are facially time-barred by Texas' two-year statute of limitations from the time of injury for personal injury actions. Plaintiff developed her alleged injuries on July 29, 2015, more than 2 years before she filed suit on August 3, 2017. All of Plaintiff's claims, therefore, should be dismissed.

Second, Plaintiff's failure-to-warn claims are subject to Section 82.007(a) of the Texas Civil Practice & Remedies Code, which provides that Jardiance's FDA-approved warnings are presumptively adequate as a matter of law, unless Plaintiff has alleged sufficient facts regarding one of the five enumerated exceptions under Section 82.007(b). Plaintiff has not alleged sufficient facts to defeat the presumption, warranting dismissal of her claims.

Third, Plaintiff's Complaint falls woefully short of federal pleading standards, failing to distinguish among Defendants and their respective roles while pleading general, conclusory

[1] As of the date of this filing, Defendants Boehringer Ingelheim Pharma GmbH & Co. KG and Boehringer Ingelheim International GmbH have not been served in this action.

allegations that fail to place each Defendant on notice of Plaintiff's specific claims against it.[2] That Plaintiff's Complaint is devoid of the specificity required by the federal rules is not surprising, as the Complaint appears to be copied nearly verbatim from two other complaints related to different Type 2 diabetes drugs, substituting the party and drug names, and adding little, if anything, to the Complaint. Those complaints, deemed by two different federal district courts to consist "largely [of] legal conclusions," were dismissed in their entirety for failure to state a claim. *House v. Bristol-Myers Squibb Co.*, No. 3:15-cv-00894-JHM, 2017 WL 55876, at *4 (W.D. Ky. Jan. 4, 2017); *see also Fleming v. Janssen Pharm., Inc.*, 186 F. Supp. 3d 826, 836 (W.D. Tenn. 2016)). Plaintiff's Complaint should meet a similar fate.

Fourth, Plaintiff's strict liability design defect and negligent misrepresentation claims should be dismissed because they are contrary to Texas law. Texas has adopted comment k to Section 402A of the Restatement (Second) of Torts which bars strict liability design defect claims. In addition, Plaintiff's negligent misrepresentation claim fails because the elements necessary to make such a claim under Texas law are not present here.

For these reasons and those that follow, Plaintiff's entire Complaint should be dismissed.

BACKGROUND

Plaintiff alleges that she was prescribed Jardiance to treat her diabetes. *See* Compl. [D.E. 1] ¶ 32. Diabetes is a serious healthcare epidemic characterized by uncontrolled blood glucose (sugar) levels and many resulting complications. Jardiance (*empagliflozin*) was approved by the FDA in August 2014 as safe and effective for the treatment of Type 2 diabetes. *Id.* ¶ 21. It is a member of the class of medications used to treat Type 2 diabetes known as sodium-glucose co-transporter 2 ("SGLT-2") inhibitors. *Id.* ¶ 22.

[2] Lilly is filing a separate motion to dismiss all claims against it on preemption grounds, as it is not the Jardiance NDA holder.

Plaintiff alleges that she began taking Jardiance "on or about July 24, 2015 . . . to treat diabetes." *Id.* ¶ 32. "On or about July 29, 2015," Plaintiff alleges that she experienced DKA. *Id.* ¶ 37. Plaintiff's Complaint does not provide any factual statements about her alleged development of DKA, including the type and timing of her symptoms, how her condition was diagnosed, whether it has resolved, and, most importantly, how Jardiance purportedly caused her DKA to develop. In addition to developing DKA, Plaintiff alleges that she experienced "other related health complications." *Id.* ¶ 66. Though Plaintiff also alleges that Jardiance generally causes "stroke, heart attack and severe kidney damage," *id.* ¶ 136, Plaintiff does not claim that she developed or experienced any of these conditions.

Plaintiff filed her Complaint on August 3, 2017, seeking "actual, compensatory, and punitive damages" from and asserting eleven unsubstantiated claims against all Defendants based on their alleged roles (which she conflates) in the design, manufacture, marketing, advertisement, licensing, distribution, and sale of Jardiance. *Id.* ¶¶ 1, 6, 45.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcraft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "To plead facial plausibility, a plaintiff must set forth factual content that permits the courts to draw the reasonable inference that the defendant is liable." *Patrick v. Wal-Mart, Inc.*, 681 F.3d 614, 622 (5th Cir. 2012); *Hopkins v. Green Dot Corp.*, No. 5:16-cv-365-DAE, 2016 WL 4468272, at *2 (W.D. Tex. Aug. 24, 2016) (Ezra, J.). "A formulaic recitation of the elements of a cause of action or facts [that] do not permit the court to infer more than the mere possibility of misconduct fail to satisfy the pleading requirements of Federal Rule of Civil Procedure 8(a)."

Woodhouse v. Sanofi-Aventis U.S. LLC, No. EP-11-cv-113-PRM, 2011 WL 3666595, at *2 (W.D. Tex. June 23, 2011).

ARGUMENT

I. ALL OF PLAINTIFF'S CLAIMS ARE TIME-BARRED.

Plaintiff's entire Complaint, arising out of her alleged personal injuries as a result of taking Jardiance, is subject to Texas' two-year statute of limitations. *See* Tex. Civ. Prac. & Rem. Code § 16.003(a).[3] "In general, the accrual period is measured from the time of the injury." *Timberlake v. A.H. Robins Co.*, 727 F.2d 1363, 1364 (5th Cir. 1984). Here, Plaintiff alleges that she developed DKA "on or about July 29, 2015." Compl. ¶ 37. Plaintiff's lawsuit, however, was not commenced until August 3, 2017, more than two years after her alleged injuries occurred. Thus, all of Plaintiff's claims are precluded by the two-year statute of limitations.

Texas' discovery rule, applied in limited circumstances, does not save Plaintiff's claims because she fails to plead facts to support application of that rule. "The discovery rule exception defers accrual of a cause of action until the plaintiff knew or, exercising reasonable diligence, should have known of the facts giving rise to the cause of action." *Computer Assocs., Int'l v. Altai, Inc.*, 918 S.W.2d 453, 455 (Tex. 1996). The discovery rule does not toll statute of limitations when "some injury is known but the full extent of injury and cause are unknown." *Yalamanchili v. Mousa*, 316 S.W.3d 33, 38 (Tex. App.-Houston [14th Dist.] 2010, pet. denied).

[3] A plaintiff "may not recast [her] claim in the language of another cause of action to avoid limitations." *Crowder v. Am. Airlines, Inc.*, No. 05-99-00661, 2000 2000 WL 471520, at *2 (Tex. App.-Dallas Apr. 25, 2000), pet. denied); *accord, e.g., McCoy v. Dallas Area Rapid Transit*, No. 05-10-01478-CV, 2011 WL 5864038, at *2 (Tex. App.-Dallas Nov. 18, 2011, no pet.). Thus, although Plaintiff alleges breach-of-warranty and fraud claims, which are generally subject to a four-year statute of limitations, *see* Tex. Bus. & Com. Code § 2.725(a)); Tex. Civ. Prac. & Rem. Code § 16.004(a)(4), in reality, these are personal injury claims subject to the two-year statute of limitations.

Plaintiff need not know "the specific cause of the injury; the party responsible for it; the full extent of it, or the chances of avoiding it." *PPG Indus., Inc. v. JMB/Hous. Ctrs. Partners Ltd. P'ship*, 146 S.W.3d 79, 93-94 (Tex. 2004).

"A statute of limitations may support dismissal under Rule 12(b)(6) where it is evident from the plaintiff's pleadings that the action is barred and the pleadings fail to raise some basis for tolling or the like." *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003). Here, Plaintiff offers no facts to support any contention that the limitations period was tolled beyond her alleged diagnosis of DKA on July 29, 2015. Indeed, Plaintiff pleads ***no facts*** regarding the circumstances surrounding her development of DKA, including the type and timing of her symptoms, how her condition was diagnosed, and whether she discontinued Jardiance after her alleged diagnosis. As a result, all of Plaintiff's claims, which accrued on July 29, 2015, are facially time-barred by Texas' two-year statute of limitations. *See Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 979 (S.D. Tex. 2012) (finding "on the face of [plaintiff's] [c]omplaint" that claim was barred by statute of limitations and was not saved by discovery rule, because plaintiff failed to "plead facts suggesting that she may avail herself of the discovery rule").

II. THE TEXAS CIVIL PRACTICE AND REMEDIES CODE SECTION 82.007 REQUIRES DISMISSAL OF PLAINTIFF'S FAILURE-TO-WARN CLAIMS.

All of Plaintiff's claims predicated on a failure-to-warn, fraud-by-omission theory fail because, pursuant to Section 82.007 of the Texas Civil Practice & Remedies Code, Defendants adequately warned Plaintiff's prescribing physician[4] about the risks of Jardiance as a matter of

[4] The Texas Supreme Court has adopted the learned intermediary doctrine, which states that "a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012). Thus, the relevant warnings here extended to Plaintiff's prescribing physician and not to Plaintiff herself.

law. In products liability actions[5] against pharmaceutical drug manufacturers, Section 82.007 "provides that an FDA-approved warning label is presumed to be an adequate warning, unless the plaintiff can satisfy one of five enumerated exceptions." *Thurston v. Merck & Co.*, 415 F. App'x 585, 586 (5th Cir. 2011) (per curiam) (citation omitted); *see also Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 206 (5th Cir. 2008) (section 82.007 creates a "statutory presumption of non-liability" for pharmaceutical drug manufacturers). Section 82.007(a) provides that, in an action alleging injury caused by a failure to provide adequate warnings or information regarding a pharmaceutical product, "there is a rebuttable presumption" that defendants "are not liable" for failing to provide adequate warnings or information, if "the warnings or information that accompanied the product in its distribution were those approved by the [FDA]."

To rebut Section 82.007(a)'s presumption of adequacy, a plaintiff must plausibly plead that one of the five specifically enumerated exceptions applies. *See, e.g.*, *Thurston*, 415 F. App'x at 586 (affirming dismissal because the "complaint [did] not plead facts sufficient to meet any of the [Section 82.007(b)] exceptions"). Because the FDA approved Jardiance's warnings and because Plaintiff has not plausibly pled that any of the exceptions applies, Plaintiff's failure-to-warn claims fail as a matter of law and should be dismissed with prejudice.

A. Section 82.007(a)'s Presumption of Adequacy Applies to Plaintiff's Failure-to-Warn Claims regarding Defendants' FDA-Approved Warnings for Jardiance.

Plaintiff's "Product Liability – Failure to Warn (Strict Liability)" claim, Compl. at 13, seeks recovery for "personal injuries suffered as a proximate result of being prescribed and

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[5] Product liability actions are defined broadly for purposes of Section 82.007(a)(1) as "any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." Tex. Civ. Prac. & Rem. Code § 82.001(2).

ingesting JARDIANCE," (*id.* ¶ 6), and thus, is a "products liability action" within the meaning of Section 82.007(a).[6] Section 82.007(a)(1)'s presumption of adequacy applies to Plaintiff's failure-to-warn claims, because the Prescribing Information that contains the warnings that accompany Jardiance's distribution "were those approved by the United States Food and Drug Administration." Tex. Civ. Prac. & Rem. Code § 82.007(a). Plaintiff admits that "[i]n August 2014, the FDA approved . . . JARDIANCE (*empagliflozin*) for the treatment of Type II diabetes," Compl. ¶ 21, and the Complaint does not (and cannot) allege that the FDA had not approved the warnings in the Jardiance Prescribing Information at the time Plaintiff allegedly began taking it. Because Plaintiff does not allege that Jardiance was distributed without the proper FDA-approved warnings, Jardiance's "FDA-approved warning label is presumed to be an adequate warning" under Section 82.007(a), warranting dismissal of her failure-to-warn claims. *Thurston*, 415 F. App'x at 586; *see also Lofton v. McNeil Consumer & Specialty Pharm.*, 682 F. Supp. 2d 662, 675-76 (N.D. Tex. 2010) (granting judgment as a matter of law under Section 82.007(a) on failure-to-warn claims regarding over-the-counter drug), *aff'd*, 672 F.3d 372 (5th Cir. 2012); *see also Anderson v. Abbott Labs.*, No. 3:11-cv-1825-L, 2012 WL 4512484, at *4 (N.D. Tex. Sept. 30, 2012) (noting that Section 82.007(a) creates a presumption that the warning in an FDA-approved label is adequate as a matter of law).

B. Plaintiff's Complaint Does Not Plausibly Allege Off-Label Promotion or Use to Rebut the Presumptive Adequacy of Jardiance's FDA-Approved Warnings.

Plaintiff fails to allege any facts in her Complaint to establish one of the five specifically enumerated exceptions under Section 82.007(b). Plaintiff asserts, without any factual support, that "Defendants have marketed and continued to market JARDIANCE for off label purposes,

[6] Plaintiff's other claims, including those for negligence, gross negligence, breach of express and implied warranty, fraud, and misrepresentation, as described *infra*, are predicated on a failure-to-warn, fraud-by-omission theory and therefore similarly should be dismissed.

including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics" and that "Defendants were aware that consumers, including Plaintiff, would use JARDIANCE for . . . weight loss, and reduced blood pressure." Compl. ¶¶ 25,135. These allegations are insufficient to establish that the off-label promotion exception applies. To obtain the benefit of that exception, Plaintiff must plausibly plead that (1) Jardiance salespersons or other employees "specifically promoted" Jardiance to Plaintiff's prescribing physician; (2) "for an off-label indication"; and (3) "such promotions caused [Plaintiff's prescribing physician] to prescribe [Jardiance] to [Plaintiff]." *Anderson*, 2012 WL 4512484, at *4.

First, Plaintiff's Complaint contains no facts or allegations establishing that Defendants specifically promoted Jardiance to Plaintiff's prescribing physician for an indication not approved by the FDA and that such off-label promotion caused Plaintiff's prescribing physician to prescribe Jardiance to Plaintiff for an off-label use. The United States District Court for the Southern District of Texas dismissed with prejudice failure-to-warn claims involving Farxiga, a drug in the same SGLT-2 inhibitor class of drugs as Jardiance, for failure to "plead and prove that the prescribing physician was influenced by the off-label marketing efforts" in support of the off-label exception under Section 82.007(b)(3)(A). *See* Order on Motion to Dismiss, *Quintanilla v. Bristol-Myers Squibb Co.*, No. 2:16-cv-00172 [D.E. 27] (S.D. Tex. Oct. 25, 2016) (hereinafter "*Quintanilla* Order"), attached hereto as Exhibit 1; *accord Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 777 (S.D. Tex. 2008), *aff'd*, 321 F. App'x 350 (5th Cir. 2009). Instead, Plaintiff's Complaint merely offers conclusory statements and formulaic recitations regarding Defendants' alleged off-label promotion of Jardiance to Plaintiff's unnamed prescribing physician. This is insufficient as a matter of law.

Second, Plaintiff "has not identified a single communication containing [off-label marketing] representations, has not identified the source of such communications (other than suggesting the Defendants, jointly), has not stated what was communicated to her, and she has not identified her prescribing physician, much less what he or she was told about [Jardiance] or what he or she told [Plaintiff] about [Jardiance]," requiring dismissal of her claim. *Quintanilla* Order at 5; *see also Anderson*, 2012 WL 4512484, at *5 (dismissing complaint with prejudice even where plaintiffs alleged that defendants' sales representatives "detailed" named prescribing physician and "encouraged him" to prescribe drug for off-label purposes).

Third, Plaintiff does not allege that she was prescribed Jardiance, or actually used it, for an off-label indication. *See* Tex. Civ. Prac. & Rem. Code § 82.007(b)(3) ("The claimant may rebut the presumption . . . by establishing that . . . the product was used [off-label] as recommended, promoted, or advertised."). To the contrary, Plaintiff alleges she "began taking JARDIANCE per her doctor's instructions, primarily to treat diabetes" Compl. ¶ 32, and does not allege that she took Jardiance as a weight-loss or blood-pressure medication, or for any other alleged off-label use. *See also, e.g., id.* ¶ 35 ("Plaintiff agreed to initiate treatment with JARDIANCE in an effort to reduce her blood sugar."). Because Plaintiff used Jardiance "for its intended and approved purpose," namely to treat her diabetes, she "cannot use [section] 82.007(b)(3) to overcome the presumption of non-liability." *Cooper v. Pfizer*, No. H-14-3705, 2015 WL 2341888, at *2-3 (S.D. Tex. May 13, 2015) (dismissing claims with prejudice where off-label use claims were directly contradicted by other allegations in the complaint).

C. Plaintiff Does Not Plausibly Allege that Any Other Exception Applies.

Plaintiff's Complaint also fails to establish that any other relevant exception applies. Section 82.007(b)(1) does not apply because Plaintiff makes no allegation that Defendants

withheld from or misrepresented any information about Jardiance to the FDA. While Plaintiff cursorily claims that "Defendants . . . provide[ed] false and misleading information with regard to JARDIANCE's safety to regulatory agencies," Compl. ¶ 94, the Fifth Circuit has determined that federal law preempts the exception contained within Section 82.007(b)(1), "unless the FDA itself has found fraud." *Lofton*, 672 F.3d at 380. The Complaint contains no allegations that the FDA has found fraud, and thus, Section 82.007(b)(1) does not apply.

Section 82.007(b)(2) likewise does not apply because the Complaint does not contain any allegations that the FDA ever ordered Defendants "to remove [Jardiance] from the market" or that the FDA ever "withdr[ew] its approval of [Jardiance]," as would be required to even argue that the exception is applicable. Tex. Civ. Prac. & Rem. Code § 82.007(b)(2).

Nor does § 82.007(b)(4) apply, because this exception only applies to prescribers, not manufacturers or sellers like Defendants. Plaintiff does not allege that Defendants "prescribed" Jardiance for any use or that Plaintiff's prescribing physician was an agent or independent contractor of Defendants. *See Murthy*, 2012 WL 6020157, at *5 (finding Section 82.007(b)(4) inapplicable to defendant that did not prescribe drug unless prescribing physician "was an agent or independent contractor" of the non-prescribing defendant).

Finally, Section 82.007(b)(5) does not apply, because Plaintiff's Complaint does not allege that Defendants bribed or improperly influenced any public official in violation of 18 U.S.C. § 201, as required to obtain the benefit of that exception. Tex. Civ. Prac. & Rem. Code § 82.007(b)(5). Because Plaintiff's Complaint "does not plead facts sufficient to meet any of the exceptions" to Section 82.007(a)'s presumption of adequacy, Plaintiff's failure-to-warn claims fail as a matter of law and should be dismissed with prejudice. *Thurston*, 415 F. App'x at 586.

III. PLAINTIFF'S COMPLAINT DOES NOT PLAUSIBLY ALLEGE ANY CAUSE OF ACTION.

Even if the Court finds that Plaintiff's claims are not time-barred or that Plaintiff's claims are not precluded by Section 82.007(a)'s presumption of adequacy, the entire Complaint should be dismissed for failure to plead sufficient facts.

A. Plaintiff Has Not Plausibly Pled Her Failure-To-Warn Claims (Counts I, IV).

Even if Plaintiff had adequately pled a statutory exception to Section 82.007(a)'s presumption of non-liability (and she has not, as explained *supra* Part II), Plaintiff's failure-to-warn claims should be dismissed because she fails to allege sufficient facts to support them. To sustain a failure-to-warn or marketing defect claim, Plaintiff must prove: "(1) a risk of harm inherent in the product or which may arise from the intended or reasonably anticipated use of the product; (2) the product supplier actually knew or should have reasonably foreseen the risk of harm at the time the product was marketed; (3) the product contains a marketing defect; (4) the absence of a warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and (5) the failure to warn must constitute a causative nexus in the product user's injury." *Wright v. Ford Motor Co.*, 508 F.3d 263, 274–75 (5th Cir. 2007).

Here, Plaintiff merely has alleged that "Defendants had a continuing duty to warn Plaintiff of the dangers associated with JARDIANCE" and that "JARDIANCE contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with JARDIANCE." Compl. ¶¶ 72, 76. Such conclusory statements do not identify the allegedly inadequate warnings or how such warnings were defective, requiring dismissal of the claims. *See, e.g., Gonzalez v. Bayer Healthcare Pharm.*, Inc., 930 F. Supp. 2d 808, 821 (S.D. Tex. 2013) (dismissing claim where plaintiff did not allege "facts specifically showing that the warnings on the [product at issue] were inadequate, nor even more so, that the allegedly inadequate warning was the producing cause of [p]laintiff's injuries"); *see also Woodhouse,*

2011 WL 3666595, at *4 (finding plaintiff failed to state strict liability claim because she merely recited elements of claim "without specific factual allegations"); *Fleming*, 186 F. Supp. 3d at 836 (finding plaintiff made "only conclusory statements as to the failure of [d]efendants to warn about the dangers of Invokana," a drug in the same class as Jardiance, where plaintiff alleged that "Invokana contained warnings insufficient to alert consumers, including [p]laintiff, to the dangerous risks and reactions associated with Invokana"); *accord House*, 2017 WL 55876, at *4.

Plaintiff's failure-to-warn claims also fail to the extent that they are premised on a purported failure to warn Plaintiff's unnamed prescribing physician about an alleged risk of health effects she does not claim to have experienced. Compl. ¶ 3. Plaintiff only alleges that she experienced DKA, *not* that she experienced stroke, heart attack, or severe kidney damage. *Id.* ¶ 37. Similarly, Plaintiff's claims premised on an alleged failure to warn about unnamed "other related health complications," Compl. ¶ 66, are not cognizable because she does not make any attempt to tie these allegations to health complications she actually experienced. Because her Complaint fails to plausibly provide "the grounds for her entitlement to relief" in this regard, the Court should dismiss her warnings-based claims as a matter of law. *Twombly*, 550 U.S. at 561.

B. Plaintiff Has Not Plausibly Pled How Jardiance Is Defective In Support Of Her Design Defect Claims (Counts I, IX).

Under Texas law, "the findings required to establish a design defect claim are identical, regardless of the legal theory asserted." *Hyundai Motor Co. v. Rodriguez ex rel. Rodriguez*, 995 S.W.2d 661, 667 (Tex. 1999). Accordingly, Plaintiff must establish that "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). Plaintiff's design-based claims fail for two reasons.

First, Plaintiff's design defect claims contain no supporting allegations because "Plaintiff makes no factual allegations showing *how* [Jardiance] was 'defectively designed and unreasonably dangerous.'" *Steen v. Medtronic, Inc.*, No. 3:10-CV-936-L, 2010 WL 2573455, at *2 (N.D. Tex. June 25, 2010) (emphasis in original). While Plaintiff baldly alleges that Jardiance is "unreasonably defective in design" and was "designed . . . in an unsafe, defective and inherently dangerous condition," Compl. ¶¶ 176, 178, these are merely recitations of the elements of a design defect claim, not the detailed factual allegations required to support that claim. *See Woodhouse*, 2011 WL 3666595, at *4 (dismissing complaint that "recite[d] the elements for a claim that [d]efendant is strictly liable . . . without specific factual allegations").

Plaintiff alleges that the class of SGLT-2 inhibitors "are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose," and "[a]s a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease." Compl. ¶ 24. Simply repeating the mechanism of action does not support a design defect claim. In fact, at least two federal district courts confronted with this exact allegation could not "reasonably infer from the generic description of SGLT2 inhibitors' mechanism of action that [the SGLT-2 inhibitor at issue] was defective or unreasonably dangerous," and dismissed the complaints. *House*, 2017 WL 55876, at *3 (quoting *Fleming*, 186 F. Supp. 3d at 835 (the other federal district court decision dismissing a similar claim on identical grounds)). Here, Plaintiff's design claims are similarly pled, and similarly fail.

Second, Plaintiff's Complaint fails to allege a safer alternative design as required to state any claim for design defect under Texas law. *See* Tex. Civ. Prac. & Rem. Code § 82.005(a)(1) (requiring that plaintiff prove a safer alternative design by a preponderance of the evidence for

design defect claims).[7] Plaintiff attempts to plead that "the existence of other [unnamed] diabetes medications that had a more established safety profile and a considerably lower risk profile" demonstrates the existence of a safer alternative design to Jardiance. Compl. ¶ 182. The crux of Plaintiff's allegation, however, is not that Jardiance "should have been *safer*," but that it "should have been a *different product*" – a design claim that does not stand in Texas. *Massa v. Genentech, Inc.*, No. 11-cv-0070, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012) (emphasis in original). That is, "plaintiff cannot demonstrate the existence of a 'safer alternative design' by pointing to a substantially different product, even when the other product has the same general purpose as the allegedly defective product." *Id.* Plaintiff's failure to allege the availability of a safer alternative design requires dismissal of her claims. *Barragan v. Gen. Motors LLC*, No. SA-15-cv-854-DAE, 2016 WL 3519675, at *4 (W.D. Tex. June 22, 2016) (Ezra, J.) (dismissing certain design defect claims that failed to plead existence of safer alternative design).[8]

C. Plaintiff Has Not Plausibly Pled Her Negligence Claims (Counts III-IV).

To prevail on a negligence claim, Plaintiff must show (1) a legal duty owed by Defendants to Plaintiff; (2) a breach of that duty; and (3) damages proximately caused by the

[7] Although Section 82.005(a) by its terms does not apply in pharmaceutical cases, courts have nonetheless looked to Section 82.005(a) to define what a "safe alternative design" is in the context of a pharmaceutical products liability case. *See Conklin v. Novartis Pharm. Corp.*, No. 9:11-cv-178, 2012 WL 4127301, at *4 n.8 (E.D. Tex. Sept. 18, 2012) (granting defendant's motion for summary judgment on strict liability design defect claim because plaintiff's experts did not sufficiently establish a safer alternative design, and looking to Section 82.005(a) because "the court has found no prescription drug design defect case in Texas that looks to anything other than Section 82.005 to define what a 'safe alternative design' is.")

[8] To the extent Plaintiff argues that defendants should have altered the formulation of Jardiance after the FDA approved it, federal law preempts Plaintiff's design defect claims for the reasons fully set forth in Defendant Eli Lilly and Company's Memorandum In Support Of Its Motion To Dismiss, filed contemporaneously, which BIPI joins and incorporates herein by reference. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298 (6th Cir. 2015). If the Court dismisses Plaintiff's design defect claims against Lilly because Jardiance's design could not have been changed without FDA approval, it should dismiss those claims against BIPI for the same reasons.

breach. *See Cook v. T-Mobile USA, Inc.*, No. 3:14-CV-2907-P, 2015 WL 11120973, at *2 (N.D. Tex. June 2, 2015). To establish gross negligence, a plaintiff must prove two additional elements by clear and convincing evidence: (1) that from the actor's standpoint, the act or omission complained of involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and (2) that the actor had actual subjective awareness of the risk involved but nevertheless proceeded in conscious indifference of the rights and safety or welfare of others. Tex. Civ. Prac. & Rem. Code § 41.003(a)(3*); Lee Lewis Constr., Inc. v. Harrison*, 70 S.W.3d 778, 785 (Tex. 2001). This Court should dismiss both of Plaintiff's negligence-based claims as insufficiently plead for the reasons stated below.

i. Plaintiff Has Not Pled a Plausible Negligence Claim Under Any Of The Theories Set Forth In Her Complaint.

To the extent that Plaintiff's "catch-all" negligence claim is premised on an alleged failure to warn about Jardiance's alleged risks, *see, e.g.*, Compl. ¶¶ 107-08, 112, 113(d)-(h), Section 82.007(a)'s presumption that Jardiance's warning label was adequate as a matter of law governs, warranting dismissal for the same reasons that Plaintiff's strict liability failure-to-warn claim fails. *See, e.g.*, *Quintanilla* Order at 7-8 (dismissing negligence claim premised on failure-to-warn for same reasons as strict liability failure-to-warn claims); *Anderson*, 2012 WL 4512484, at *7 (dismissing negligence claims where plaintiff failed to rebut statutory presumption under Section 82.007(a)); *Gonzalez*, 930 F. Supp. 2d. at 820 (dismissing negligence claim that was a "disguised failure-to-warn" claim subject to Section 82.007").

To the extent that Plaintiff's negligence claim is premised on Defendants' alleged failure to properly design Jardiance, *see, e.g.*, Compl. ¶¶ 104, 108-112, 113(a)-(d), the claim fails for the same reasons that her strict liability design defect claim fails. *See Conklin*, 2012 WL 4127301, at *4–5 (where "[plaintiff] cannot prevail on her design defect claim," plaintiff's negligence

claim "that simply re-packages the design defect claim" also fails); *Morgan v. Medtronic, Inc.*, 172 F. Supp. 3d 959, 968-70 (S.D. Tex. 2016) (negligence claim based upon defective design requires proof of safer alternative design).

Plaintiff's negligence claim based on an alleged manufacturing defect, *see* Compl. ¶¶ 104, 108, 111-12, 113(d), fares no better, because it contains "no more than conclusory allegations that there was a manufacturing defect" and alleges no facts about how the Jardiance she ingested "deviate[d] in its construction or quality, from the specifications or planned output in a manner that render[ed] [Jardiance] unreasonably dangerous." *Rojas v. Teva Pharm. USA, Inc.*, 920 F. Supp. 2d 772, 779 (S.D. Tex. 2013). More is required under Texas law. *Id.*

Finally, to the extent that Plaintiff premises her negligence claim on Defendants' alleged failure to adequately test Jardiance, the Complaint offers nothing but conclusory allegations that Defendants "fail[ed] to properly and thoroughly test Jardiance," *see id.* ¶ 113(a), and must be dismissed because Plaintiff "does not plead any facts to support" these allegations. *Murthy*, 847 F. Supp. 2d at 977. Moreover, Plaintiff's claims for negligent testing are "inextricably intertwined with" her failure-to-warn claims, causing these claims to fail for the same reasons as her failure-to-warn claims. *Quintanilla* Order, at 7 (dismissing negligent failure to test claim).

ii. Plaintiff's Gross Negligence Claim Fails For The Same Reasons.

Plaintiff's gross negligence claim merely restates her implausible failure-to-warn claims, asserting that "Defendants failed to provide adequate warnings" about Jardiance's alleged side effects, Compl. ¶ 96; *see also id.* ¶ 112, and therefore should be dismissed for the same reasons as her failure-to-warn claims. *See Gonzalez*, 930 F. Supp. 2d at 820 (finding gross negligence claim was a "disguised" failure-to-warn claim subject to Section 82.007(a)). Moreover, because Plaintiff has not plausibly pled her claim for negligence, her gross negligence claim necessarily

fails. *Sanders v. Herold*, 217 S.W.3d 11, 20 (Tex. App–Houston [1st Dist.] 2006, no pet.) (holding that "one's conduct cannot be grossly negligent without being negligent").

D. Plaintiff Has Not Pled Pre-Suit Notice or Sufficient Facts In Support Of Her Breach of Warranty Claims (Counts V-VI).

Where Plaintiff's breach of warranty claims are predicated on an alleged failure to provide adequate warnings, *see* Compl. ¶¶ 122-24 (referencing "incomplete prescribing information"), 136-37 (referencing Jardiance's "dangerous propensities" and lack of adequate testing), Section 82.007(a)'s presumption that Jardiance's labeling was adequate as a matter of law governs, requiring dismissal of these claims. *Gonzalez*, 930 F. Supp. 2d at 820 (dismissing breach of express and implied warranty claims that were failure-to-warn claims in disguise).

Plaintiff's breach of warranty claims fail for two additional reasons. First, Plaintiff fails to plead that she provided Defendants with the requisite pre-suit notice of the alleged breaches. To bring a breach of warranty claim, a plaintiff "must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from remedy." Tex. Bus. & Com. Code § 2.607(c)(1). Nowhere in Plaintiff's Complaint does Plaintiff plead that she notified Defendants "within a reasonable time" of any alleged breach, thereby barring her warranty claims. *Morgan*, 172 F. Supp. 3d at 970 (dismissing breach of warranty claims with prejudice for failure to allege pre-suit notice).

Second, Plaintiff's breach of warranty claims fail because she cannot base her claims on an alleged warranty that Jardiance was "safe and effective for use," "safe and fit for its intended purposes," "of merchantable quality," "did not produce any dangerous side effects," and/or "had been adequately tested." Compl. ¶¶ 121-24; *see also id.* ¶¶ 136-37. Such allegations amount to nothing more than formulaic recitations of the elements of such claims, requiring their dismissal. *See, e.g., Steen*, 2010 WL 2573455, at *3 (dismissing claims for breach of express and implied

warranty that product "was of merchantable quality and was safe and fit for the purpose intended," because plaintiff did not allege "when and how he received notice of such warranties"); *see also House*, 2017 WL 55876, at *5-6 (dismissing express warranty claim based on representations that drugs were "safe and fit for their intended purposes, were of merchantable quality, [and] did not produce any dangerous side effects").

E. Plaintiff's Claims For Fraud and Misrepresentation Fail Because Plaintiff Does Not Plead These Claims With Particularity (Counts VII-VIII, X-XI).

To the extent Plaintiff's claims for fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, and fraud are failure-to-warn claims in disguise, they must be dismissed for the same reasons as her strict liability failure-to-warn claims. *Gonzalez*, 930 F. Supp. 2d at 820 (fraud-by-omission claims subject to Section 82.007(a)).

The Court should dismiss these claims for the additional reason that Plaintiff has not stated "with particularity the circumstances constituting fraud," a requisite for each of these claims. FED. R. CIV. P. 9(b). To plead such claims with particularity, Texas law requires "'time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby.'" *Woodhouse*, 2011 WL 3666595, at *5. Plaintiff fails to provide any detail concerning the time, place, and content of any alleged misrepresentation, concealment, or other fraudulent act by Defendants. Moreover, Plaintiff names four Defendants in this lawsuit, yet fails to distinguish between each or any Defendant's involvement in the alleged fraudulent acts, omissions, and misrepresentations. Plaintiff, *inter alia*, alleges that "Defendants" collectively misrepresented that Jardiance was safe through their "labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions," misrepresented the "properties and effects of JARDIANCE," used unspecific "sales and marketing documents" that contained representations

contrary to Defendants' knowledge of Jardiance's "risks and injuries," and "distributed false information." Compl. ¶¶ 152(a), 160, 204, 212. Such threadbare allegations do not satisfy Rule 8(a) or Rule 9(b), requiring dismissal of Plaintiff's claims. *See Woodhouse*, 2011 WL 3666595, at *5 (dismissing fraud claim based on defendants' representation that medication was "safe" for failing to plead with particularity); *see also House*, 2017 WL 55876, at *8-9 (dismissing fraud, fraudulent misrepresentation and negligent misrepresentation claims).

IV. PLAINTIFF'S STRICT LIABILITY DESIGN DEFECT AND NEGLIGENT MISREPRESENTATION CLAIMS FAIL BECAUSE THEY ARE NOT RECOGNIZED UNDER TEXAS LAW (COUNTS I, VIII).

Texas has adopted comment k to Section 402A of the Restatement (Second) of Torts. *See Woodhouse*, 2011 WL 3666595, at *3. Under Texas law and comment k, "prescription drugs cannot be found unreasonably dangerous and a seller cannot be held strictly liable where the drugs are accompanied by an adequate warning." *McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 910 (W.D. Tex. 2013), *aff'd* 751 F.3d 694 (5th Cir. 2014). "[A]llow[ing] plaintiffs to sue for defective design of prescription drugs would provide a disincentive to companies to develop new drugs and would allow juries to second-guess the FDA's approval of the drugs." *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002).

Plaintiff's Complaint is devoid of facts alleging that the Jardiance she ingested was not properly prepared. While Plaintiff alludes to a manufacturing defect, Plaintiff's conclusory allegations are insufficient to state a claim. *See supra* at 16. Furthermore, as discussed *supra* at Part II, Defendants' warnings accompanying Jardiance were adequate as a matter of law under Section 82.007. The FDA approved Jardiance's warnings, and Plaintiff has not alleged any facts to overcome the presumptive adequacy of those warnings. Because Plaintiff has not and cannot allege that "Defendant[s] improperly prepared or marketed [Jardiance], that Defendant[s] did not

give proper warning, or that the risk of [Jardiance's] side effects are unreasonable," her design defect claim fails. *Woodhouse*, 2011 WL 3666595, at *4.

Plaintiff's negligent misrepresentation claim also fails as a matter of law, because Texas does not recognize a tort for negligent misrepresentation leading to physical harm, as opposed to pecuniary loss. *Roberts v. Zev Techs., Inc.*, No. 1:15-cv-309, 2015 WL 7454688, at *5 (W.D. Tex. Nov. 23, 2015). The only relief for negligent misrepresentation available under Texas law is under section 552B of the Restatement (Second) of Torts, which requires a showing that "the defendant supplie[d] 'false information' for the guidance of others in their business." *See Fed. Land Bank Ass'n v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991) (adopting Restatement (Second) of Torts § 552B). Because nothing in Plaintiff's Complaint suggests that she purchased Jardiance for business purposes, Plaintiff's negligent misrepresentation claim should be dismissed with prejudice. *Roberts*, 2015 WL 7454688, at *5.

CONCLUSION

For the reasons outlined above, Plaintiff's Complaint should be dismissed in its entirety.

Dated: September 27, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September, 2017, a true and correct copy of the foregoing document was electronically filed with the Court through the CM/ECF system, which will send notification of such filing to all parties.

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